



Exhibit 2

Premarket Approval (PMA)


U.S. Department of Health & Human Services


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Note: this medical device record is a supplement. The device description may have changed. Be sure to look at the [original PMA](#) to get an up-to-date view of this device.

Trade Name	JUVEDERM ULTRA XC AND JUVEDERM ULTRA PLUS XC
Classification Name	Implant, Dermal, For Aesthetic Use
Generic Name	Juvederm Gel Implants
Applicant	ALLERGAN
PMA Number	P050047
Supplement Number	S005
Date Received	08/18/2008
Decision Date	01/07/2010
Product Code	LMH [Registered Establishments With LMH]
Advisory Committee	General & Plastic Surgery
Clinical Trials	NCT00653861
Supplement Type	Normal 180 Day Track
Supplement Reason	Change Design/Components/Specifications - Component
Expedited Review Granted?	No
Combination Product	Yes
Review Memo	Review Memo
Approval Order Statement	Approval for the addition of 0. 3% lidocaine into juvederm ultra and juvederm ultra plus. The device, as modified, will be marketed under the trade name juvederm ultra xc and juvederm ultra plus xc and is indicated for injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
Approval Order	Approval Order

Page Last Updated: 03/23/2015


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